

Card 01

9-10

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| ID# | | | | FORM | 0 | 5 | V | 1 |

EARLY PREGNANCY STUDY

HUSBAND'S QUESTIONNAIRE

Thank you very much for completing this questionnaire. All information you provide is entirely confidential and will be used only for group statistics. Your name will not be associated with your information.

INSTRUCTIONS: STATEMENTS IN ALL CAPITAL LETTERS ARE INSTRUCTIONS TO YOU. Please use pencil to record your answers and do not skip any question unless instructed to do so. If your answer does not fit one of the responses provided, feel free to write in your answer. With careful reading of instructions, it takes ten to fifteen minutes to complete the questionnaire properly.

ID#

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Card 04
9-10

MEDICATIONS SUPPLEMENT

HUSBAND'S QUESTIONNAIRE

ENTER RESPONSES TO C2 THRU C6 ON MEDICATION TABLE BELOW.

C2. Please list the names of all these medication on the table below and answer C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS.

C3. What was your usual dosage for (MEDICATION NAMED)?

C4. How often did you take this medication?

C5. Is this a prescription medication?

C6. How many days or weeks did you take this medication during the last 13 weeks?

| C2 MEDICATION NAME | | C3 DOSAGE | | C4 SCHEDULE | C5 PRESCRIPTION? | C6 TIME TAKEN |
|--------------------|-------------|-----------|-------------|-------------|----------------------------------|----------------------------------|
| 11-14 | OFFICE CODE | 15-18 | OFFICE CODE | 19 X DAY | (1) YES _____ (2) NO _____ 21 | 22-23 DAYS 24-25 WEEKS |
| 26-29 | OFFICE CODE | 30-33 | OFFICE CODE | 34 X DAY | (1) YES _____ (2) NO _____ 36 | 37-38 DAYS 39-40 WEEKS |
| 41-44 | OFFICE CODE | 45-48 | OFFICE CODE | 49 X DAY | (1) YES _____ (2) NO _____ 51 | 52-53 DAYS 54-55 WEEKS |
| 56-59 | OFFICE CODE | 60-63 | OFFICE CODE | 64 X DAY | (1) YES _____ (2) NO _____ 66 | 67-68 DAYS 69-70 WEEKS |
| 71-74 | OFFICE CODE | 75-78 | OFFICE CODE | 79 X DAY | (1) YES _____ (2) NO _____ 81 | 82-83 DAYS 84-85 WEEKS |
| 86-89 | OFFICE CODE | 90-93 | OFFICE CODE | 94 X DAY | (1) YES _____ (2) NO _____ 96 | 97-98 DAYS 99-100 WEEKS |

GO TO SECTION D

SECTION A - TOBACCO HISTORY

A1. Have you ever smoked a total of 100 cigarettes in your lifetime?

(1) YES _____

11

(2) NO _____ GO TO A7

A2. At what age did you start smoking cigarettes? DO NOT INCLUDE "EXPERIMENTAL" SMOKING BUT RECORD THE AGE AT WHICH YOU STARTED SMOKING ON A REGULAR BASIS.

12-13

AGE

A3. Are you currently smoking? CURRENT SMOKING REFERS TO SMOKING DURING THE LAST TWO WEEKS.

(1) YES _____ GO TO A5

14

(2) NO _____

A4. How old were you when you stopped smoking?

15-16

AGE

A5. Altogether, how many years have you smoked, subtracting out times when you were not smoking?

17-18

YEARS

A6. On an average day, how many cigarettes a day do/did you smoke? (20 CIGARETTES TO A PACK)

19-20

CIGS

A7. Did you smoke any marijuana during the last three months?

(1) YES _____

21

(2) NO _____ GO TO A9

A8. How many times did you smoke marijuana during the last three months?

22-23

TIMES

A9. Did your mother smoke cigarettes when she was pregnant with you?
DK IS OUR ABBREVIATION FOR "DON'T KNOW."

(1) YES _____

(2) NO _____

24

(8) DK _____

A10. When you were younger than 10 years old, did your mother smoke in your home on a regular basis?

(1) YES _____

(2) NO _____

25

A11. When you were younger than 10 years old, did your father smoke in your home on a regular basis?

(1) YES _____

(2) NO _____

26

A12. When you were younger than 10 years old, did anyone else in your household smoke on a regular basis?

(1) YES _____

(2) NO _____

27

SECTION B - BEVERAGE INFORMATION

PLEASE USE THE SPACE BELOW EACH QUESTION FOR ANY COMMENTS OR MATH RELATED TO THAT QUESTION.

- B1. How many cups of brewed caffeinated coffee did you drink in the last month? _____ 28-30
- B2. How many cups of instant caffeinated coffee did you drink in the last month? _____ 31-33
- B3. How many cups or glasses of hot or iced non-herbal tea did you drink in the last month? _____ 34-36
- B4. How many 12 oz. bottles or cans of beer did you drink in the last month? _____ 37-39
- B5. How many 4 oz. glasses of wine did you drink in the last month? _____ 40-42
- B6. How many 1½ oz. shots of hard liquor did you drink in the last month? Include mixed drinks and count Martinis, Black Russians, etc., as 2 drinks since they have double the amount of alcohol. _____ 43-45
- B7. How many servings of the following soft drinks did you drink in the last month?
- COLAS: Coke, Diet Coke, Tab, Pepsi, Diet Pepsi, Pepsi Light, Shasta Cola, Diet Shasta, Chek Cola. _____ 46-48
- OTHERS: Dr. Pepper, Sugar Free Dr. Pepper, Mello Yello, Mountain Dew, Sun Drop, Cheerwine, Barq's Root Beer, Barq's Sugar Free Root Beer. _____ 49-51

PLEASE READ THIS PAGE CAREFULLY BEFORE GOING TO THE NEXT PAGE
AND REFER TO THIS PAGE AS YOU COMPLETE THE MEDICATIONS TABLE.

In this section, we want to obtain information on all medications you have taken during the past three months (13 weeks). This page provides you with information on how to fill out the table. Please enter your information on the table on the next page.

C2. Please list the names of all these medications on the medication table and answer C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS.

If you do not know the exact name of the medication, record the type of medication such as antibiotic, cough syrup, etc. USE THE MEDICATIONS SUPPLEMENT IF YOU USED MORE THAN FOUR MEDICATIONS. BE SURE NOT TO WRITE IN THE OFFICE CODE BOXES.

C3. What was your usual dosage for (MEDICATION NAMED)?

The dosage refers to the amount of medication you take each time you use the medication. Dosages are commonly expressed as milligrams (mgs), capsules, pills, tablets, tablespoons, teaspoons, ounces, injections or cubic centimeters (cc). Be sure to record the amount and type of dosage such as 2 tablets, 250 mgs or 1 tablespoon. You may use standard abbreviations in recording. Whenever possible, record the more precise measure such as two 500 mg tablets instead of two tablets.

C4. How often did you take this medication?

Record either the number of times a day or the number of times a week you took the medication. If the schedule for taking the medication is so variable that you cannot record a usual schedule, make notes in the comments section of the page and explain the situation. If you do make notes, be sure to indicate which medication the note refers to.

C5. Is this a prescription medication?

A prescribed medication refers to a medication filled by a pharmacist according to a physician's prescription. It does not refer to an over-the-counter medication that your doctor may have told you to take.

EXAMPLE

| | C2 MEDICATION NAME | C3 DOSAGE | C4 SCHEDULE | C5 PRESCRIPTION? | C6 TIME TAKEN |
|---|-------------------------|-----------------------|---|---|-----------------|
| | OFFICE CODE | OFFICE CODE | <input type="checkbox"/> X DAY | (1) YES _____ | _____ DAYS |
| 1 | One a day Stressgard | 1 Tablet | <input type="checkbox"/> X WEEK | (2) NO <input checked="" type="checkbox"/> | <u>13</u> WEEKS |
| | OFFICE CODE | OFFICE CODE | <input checked="" type="checkbox"/> X DAY | (1) YES <input checked="" type="checkbox"/> | <u>10</u> DAYS |
| 2 | Polycillin | one 250 mg capsule | <input type="checkbox"/> X WEEK | (2) NO _____ | _____ WEEKS |

1. John takes One-A-Day Stressgard at breakfast every day. Therefore he took 1 tablet 1 time a day for 13 weeks (there are approximately 13 weeks in this three-month period).
2. John had bronchitis and took 250 mg polycillin capsules 4 x a day for 10 days according to his doctor's prescription.

SECTION C - HUSBAND'S MEDICATIONS

Card 02

C1. Have you taken any prescription or non-prescription medications, including aspirin, digestive aids and vitamins during the past THREE months (13 weeks)?

(1) YES _____ COMPLETE C2-C6

11

(2) NO _____ GO TO SECTION D

ENTER RESPONSES TO C2 THRU C6 ON MEDICATION TABLE BELOW.

C2. Please list the names of all these medications on the table below and answer C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS.

C3. What was your usual dosage for (MEDICATION NAMED)?

C4. How often did you take this medication?

C5. Is this a prescription medication?

C6. How many days or weeks did you take this medication during the last 13 weeks?

| C2 MEDICATION NAME | C3 DOSAGE | C4 SCHEDULE | C5 PRESCRIPTION? | C6 TIME TAKEN |
|--|--|---|----------------------------------|---------------------------|
| 12-15 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 16-19 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 20 <input type="checkbox"/> X DAY 21 <input type="checkbox"/> X WEEK | (1) YES _____ (2) NO _____ 22 | 23-24 DAYS 25-26 WEEKS |
| 27-30 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 31-34 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 35 <input type="checkbox"/> X DAY 36 <input type="checkbox"/> X WEEK | (1) YES _____ (2) NO _____ 37 | 38-39 DAYS 40-41 WEEKS |
| 42-45 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 46-49 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 50 <input type="checkbox"/> X DAY 51 <input type="checkbox"/> X WEEK | (1) YES _____ (2) NO _____ 52 | 53-54 DAYS 55-56 WEEKS |
| 57-60 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 61-64 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OFFICE CODE | 65 <input type="checkbox"/> X DAY 66 <input type="checkbox"/> X WEEK | (1) YES _____ (2) NO _____ 67 | 68-69 DAYS 70-71 WEEKS |

COMMENTS:

GO TO MEDICATIONS SUPPLEMENT FOR ADDITIONAL MEDICATIONS

SECTION D - BACKGROUND QUESTIONS

D1. What is the highest grade in school or year in college that you completed?

YEARS ELEMENTARY SCHOOL _____

YEARS HIGH SCHOOL _____

YEARS COLLEGE _____

YEARS GRADUATE SCHOOL _____

| | |
|--|--|
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OFFICE
CODE

11-12

D2. How many years of vocational or technical training have you had?
THIS DOES NOT INCLUDE TRAINING FOR HIGH SCHOOL, COLLEGE OR
GRADUATE SCHOOL CREDIT._____
YEARS

13

D3. Are you currently employed?

(1) YES _____

(2) NO _____ GO TO D6

14

D4. Please describe your present job, including your complete job title and
your duties on this job. _____

| | | | |
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OFFICE CODE

15-18

D5. What is the name of the company or organization you work for and what does this
company make or do? _____

CIRCLE CODE FOR WHOLESALE, RETAIL OR OTHER:

W R O SKIP TO D9.

| | | | |
|--|--|--|--|
| | | | |
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OFFICE CODE

19-22

D6 THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY

D6. Have you ever been employed?

(1) YES _____

(2) NO _____ GO TO D9

23

D7. Please describe your most recent job, including your complete job title
and your duties on this job. _____

| | | | |
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OFFICE CODE

24-27

GO TO NEXT PAGE

D8. What is the name of the company or organization you worked for and what did this company make or do? _____

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

28-31

OFFICE CODE

CIRCLE CODE FOR WHOLESALE, RETAIL, OR OTHER: W R O

D9. Which of these categories best describes your race?

(1) AMERICAN INDIAN OR ALASKAN NATIVE _____

(2) ASIAN OR PACIFIC ISLANDER..... _____

(3) BLACK, NOT OF HISPANIC ORIGIN.... _____

32

(4) HISPANIC..... _____

(5) WHITE, NOT OF HISPANIC ORIGIN.... _____

(6) OTHER (SPECIFY) _____

D10. Were you born in the United States?

(1) YES _____ GO TO D13

(2) NO _____

33

D11. In what country were you born? _____

| | |
|--|--|
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34-35

OFFICE
CODE

D12. In what year did you first enter the U. S.?

YEAR

36-37

D13. On what date was this questionnaire completed?

_____/_____/_____
MONTH DAY YEAR

| | | | | | |
|--|--|--|--|--|--|
| | | | | | |
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38-43

OFFICE CODE

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE. YOUR SRA REPRESENTATIVE WILL PICK IT UP WHEN SHE VISITS YOUR WIFE NEXT WEEK.

If you would like to review a summary of the study, please turn the page for a copy of the text of the consent form.

CONSENT TO PARTICIPATE IN THE EARLY PREGNANCY STUDY

The National Institute of Environmental Health Sciences is conducting a study of early pregnancy, in which you are invited to participate. The data is being collected by Survey Research Associates, Inc., a firm which specializes in health studies. In this study, urine samples from women who may be pregnant will be analyzed using newly-developed and very sensitive assays for pregnancy hormone. Two assays for human chorionic gonadotropin (hCG) and one for luteinizing hormone (LH) will be used on each specimen. This study will provide information about the usefulness of these new tests, and will also provide some information about the events of early pregnancy. For example, this study may detect conceptions that are lost before a woman realizes she is pregnant. Eventually, this project may result in improved tests for pregnancy diagnosis, and may lead to a better understanding of factors that promote a healthy pregnancy.

Participants are being asked to do the following:

1. Respond to a questionnaire at the beginning and the end of the study. These questionnaires are completely confidential. They include questions on menstrual history, use of birth control, drugs and medications, and behavior related to pregnancy.
2. Collect daily urine specimens which they will freeze for 1-2 weeks, at which time the specimens will be picked up by study personnel. Urine will be collected for up to six months or 8 weeks after a missed menstrual period that is diagnosed as pregnancy.
3. Fill out a daily check-list of four pregnancy-related questions.

Participants will be paid \$10 a week for the collection and storage of these urine specimens.

The hCG assays that will be used in this study are still in the experimental stage, and in most cases will not be performed until you have completed your participation in the study. Therefore, this study will not provide you with diagnosis of your own pregnancy. You will have to obtain pregnancy diagnosis and prenatal care in the usual way. If you become pregnant in the course of this study, the investigators would like to keep in touch with you to the conclusion of your pregnancy. However, you are free to withdraw from participation in the study at any time, before or after you become pregnant.

The results of your tests will be combined with data collected from other women in order to do statistical analysis. All information in this study is completely confidential and information with your name will be stored in locked files. Although your personal test results will not be accessible by themselves you are entitled to data describing the whole study after data collection has been completed.

If you have any questions in the course of the study that cannot be adequately answered by study personnel, you are invited to directly contact the Principle Investigator, Dr. Allen J. Wilcox, of the National Institute of Environmental Health Sciences, at 541-3445.